Remarks/Arguments

The foregoing amendments in the specification and claims are of formal nature, and do not add new matter.

Prior to the present amendment, claims 39-44 were pending in this application and were rejected on various grounds. Claim 44 has been cancelled. The rejection of the remaining claims is respectfully traversed.

Priority

The Examiner states that Applicants are only entitled to the 2/22/00 priority of the PCT case. It is noted for the record that, the gene amplification data, first disclosed in US Provisional Application Serial No. 60/099,803 on September 10, 1998, the priority of which is claimed in the present application, establishes patentable utility for this case, as will be evident in the discussion below.

Gene amplification is an essential mechanism for oncogene activation. It is well known that gene amplification occurs in most solid tumors, and generally is associated with poor prognosis. As described in Example 92 of the present application, the inventors isolated genomic DNA from a variety of primary cancers and cancer cell lines that are listed in Table 8 (pages 230-234 of the specification), including primary lung cancers and colon cancers of the type and stage indicated in Table 8 (page 227). As a negative control, DNA was isolated from the cells of ten normal healthy individuals, which was pooled and used as a control (page 222, lines 34-36). Gene amplification was monitored using real-time quantitative TaqMan PCR. The gene amplification results are set forth in Table 9. As explained in the passage bridging pages 222 and 223, the results of TaqMan PCR are reported in Ct units. One unit corresponds to one PCR cycle or approximately a 2-fold amplification, relative to control, two units correspond to 4-fold, 3 units to 8-fold, etc. amplification. PRO214 showed 1.16- 2.76 fold gene amplification in a number of lung and colon tumors.

The attached Declaration by Audrey Goddard clearly establishes that the TaqMan real-time PCR method described in Example 92 has gained wide recognition for its versatility,

sensitivity and accuracy, and is in extensive use for the study of gene amplification. The facts disclosed in the Declaration also confirm that based upon the gene amplification results set forth in Table 9, one of ordinary skill would find it credible that PRO214 is a diagnostic marker of human lung and colon cancer. It is, of course, true that further research might be needed to develop PRO214 into a diagnostic product but the logic underlying Applicants' assertion that PRO214 is a diagnostic marker of lung and colon cancer is a "real world use" for the polypeptide and the claimed antibodies to this polypeptide.

Accordingly, the effective filing date of the present application is 9/10/1998.

Specification

The specification has been objected to for containing embedded hyperlink and/or other form of browser-executable code. The foregoing amendment, which deleted all embedded hyperlinks, is believed to overcome this objection.

Sequence Listing

The Examiner noted that the specification failed to recite appropriate sequence identifiers for sequences cited, for example, at page 14, line 17. Applicants will provide a new sequence listing separately to overcome the objection.

IDS

The attached IDS in compliance with 37 C.F.R. 1.98(a)(1) listing the authors, title and publication date, as requested, is believed to overcome this rejection.

Claim Rejections - 35 USC § 112, second paragraph

Claim 44 is rejected as "indefinite," absent a definition for "specific binding." Claim 44 has been canceled. Accordingly, the present rejection is believed to be moot and should be withdrawn.

Claim Rejections - 35 USC § 102(a)

Claim 39-44 are rejected under § 102(a) as being anticipated by Ruben (dated 11/18/1999) which discloses an isolated polypeptide which, the Examiner alleges, is 97% identical to the amino acid of SEQ ID NO 109 of the present application.

As discussed above, Applicants rely on the gene amplification data (Example 92) for support of patentable utility for polypeptide PRO214 and antibodies thereto, which was first disclosed in US Provisional Application Serial No. 60/099,803 on September 10, 1998, priority for which is claimed in the present application.

The effective date of the cited primary reference Ruben is 11/18/1999 which is after the effective filing date (9/10/1998) of the present application. Hence, Ruben is not appropriate prior art under 102(b) and does not anticipate the present claims.

Hence Applicants request that this rejection be withdrawn.

Claim Rejections - 35 USC § 103

Claims 39, 43, 44 as being unpatentable over Koehrer (dated May 1999) which teaches a hypothetical protein that is at least 99% identical to SEQ ID NO: 109. The Examiner acknowledges that Koehrer does not teach an antibody that binds the hypothetical protein but says that making antibodies is obvious and can be done with reasonable expectation of success. Applicants respectfully traverse this rejection.

Applicants rely on the gene amplification data (Example 92) for support of patentable utility for polypeptide PRO214 and antibodies thereto, which was first disclosed in US Provisional Application Serial No. 60/099,803 on September 10, 1998, priority for which is claimed in the present application.

The effective date of the cited primary reference Koehrer is 6/11/1999 which is after the effective filing date of the present application. Hence, Koehrer is not prior art under 35 U.S.C. §102 and not available under 35 U.S.C. §103(a) and thus, the present claims are not obvious over Koehrer.

Hence Applicants request that this rejection be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C3). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: ~~March~~ April 1, 2003

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